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10/519,295	10/31/2005	Jan Vandeputte	B-5626pct 622393-1	9162

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EXAMINER	
MERCIER, MELISSA S	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,295	VANDEPUTTE, JAN	
	Examiner	Art Unit	
	Melissa S. Mercier	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 7-21* is/are pending in the application.

4a) Of the above claim(s) *20 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 7-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-2-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed on April 2, 2007 is acknowledged.

Applicant has cancelled claims 2-6 and submitted claims 20-21. Newly submitted claims 20-21 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 1 and 7-19 are drawn to a composition, whereas, newly presented claims 20-21 are drawn to method of making and a method of treating, respectively

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-21 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1 and 7-19 are pending in the prosecution of this application.

In view of applicants remarks and amended claims, the objections to claims 5, 9-10, and 13 and the rejection of claims 2-3 under 35 USC 112, second paragraph and 35 USC 101 are withdrawn.

In view of the amendments to the claims, the rejection of claims 1, 3, 5, and 7-8 under 35 USC 102 (b) as being anticipated by Lundmark (US 6,174,535) is withdrawn.

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on April 2, 2007 is acknowledged.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 7-8, and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535).

Lundmark teaches dispersing honey in polyglycerylmethacrylate, and mixing the honey and the polyglycerylmethacrylate for a sufficient period of time to form a hydrated honey gel polymeric composition" (column 2, lines 54-56). Lundmark discloses, "the products of the present invention may be formulated into lotions, shampoos, hair conditioners, sunscreens, insect repellants and the like" (column 4, lines 60-63). Lundmark additionally discloses, a desirable component for use is a glycol. The glycol adds humectant properties to the composition (column 4, lines 18-20). Lundmark discloses, " the preferred polyglycerylmethacrylate is Lubrajel CG, a clathrate formed by the reaction of glycerin and methylmethacrylate" (column 3, lines 11-24). The presence of glycerin would exhibit the humectant qualities claimed in the instant claim.

Regarding claims 8, Lundmarks Example II discloses 3 formulations of their composition, each comprising between 26.00% and 29.00% honey (column 5, line 18).

Regarding Claims 15-16, the prior art is silent as to the peroxide number of honey and the LPS content. It is the examiners position that these properties are inherent properties of honey and therefore, would be present in the prior art teachings.

The instant claims differ from the references only in the specific percentage selected for the compositions. However, It would have been deemed prima Facie obvious to one having ordinary skill in the art at the time of the invention to optimize the percentage of humectant, polymeric gel based on acrylic monomers, honey, polymer, and water, to prepare a composition containing honey for the topical treatment of wounds because the determination of a specific percentage having the optimum therapeutic effect is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the active compounds. Therefore, the invention as Whole has been prima face obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1, 7, 9-10, 12, and 19, rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535) in view of Stout (US Patent 4,671,267).

Lundmark's teachings as they apply to Claim 1 are described above.

Lundmark does not disclose the composition can be used for the healing of wounds, the thickness of the application of the composition, and the gel being a 50% acrylamide, 50% water mixture.

Regarding Claim 9, Stout discloses, "improved therapy members useful for treating of sprains, muscle aches, orthopedic and skin injuries such as burns and other

wounds are provided which make use of a pliable, self-sustaining, moisture sorbing gel including a humectant such as glycerin entrapped within a synthetic resin polymer matrix (e.g., a matrix containing acrylic acid or acrylamide monomer moieties)" (abstract). Stout further discloses, "the gel material can be applied directly to injured skin to in effect create a temporary skin with ideal air permeability" (abstract).

Regarding Claim 12, Stout discloses in Table II and Example 4, a 50% acrylamide in water solution. The examiner is interpreting this to be a mixture that is 50% acrylamide and 50% water.

Regarding Claim 19, Stout discloses, "the preferred gel material provides an excellent dressing for the treatment of burned or otherwise injured skin. In this case a thin (for example from about 0.05 to 0.5 inches) layer of the gel material is hermetically sealed in a sterile package, and in use is simply directly applied to injured skin, without any intermediate cloth covering or the like" (column 3, lines 24-45). 0.05 to 0.5 inches converts to approximately, 1.27mm to 12.7mm, which overlaps the claimed range.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teaching of Lundmark with the teachings of Stout in order to form 'a gel material that can be applied directly to injured skin to in effect create a temporary skin with ideal air permeability. Furthermore, the moisture absorbing and desorbing properties of the gel create a moisture equilibrium between the gel, damaged skin and the atmosphere, thus promoting rapid healing" (abstract).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535) in view of in view of Stout (US Patent 4,671,267) and further in view of Dell (US Patent 4,542,012).

Lundmark's teachings as they apply to Claim 1 are described above.

Lundmark does not disclose the use of acrylamide or analog compounds consisting of diacetone acrylamide, vinyllactam, N-alkylated acrylamide, N,N-diakylated acrylamide, N-vinylpyrrolidone, or acryloylmorpholin.

Stout teaches the use of acrylamide as a monomer, however, Stout does not teach the use of analog compounds.

Dell discloses, "a dermatologically acceptable, film-forming composition which comprises a film-forming polymer and, as a broad spectrum antimicrobial agent. The compositions when applied to the skin from a fugitive solvent form a substantially water-insoluble, tack-free, flexible film, which adheres to the skin, releases the antimicrobial agent. (abstract).

Dell disclosed the polymer being "a polyvinylpyrrolidone polymer which is the free-radical-polymerization reaction product of at least N-vinylpyrrolidone and a vinyl-functional compound" (column 2, lines 43-47).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have expanded upon the teachings of Lundmark and Stout, with the polymer taught by Dell, in order to form "a good film-forming composition should be dermatologically-acceptable and capable of application to skin conveniently as a solution in a dermatologically-acceptable, volatile solvent. The film resulting from

application of such a solution should be bacteria-impermeable, water-insoluble, nontacky and should permit facile transmission of water vapor there through. It should adhere suitably to skin and be capable of releasing the antimicrobial agent onto the skin over a period of time to promote asepsis for a suitably long period of time" (column 2, lines 3-24).

The Applicant would have a reason expectation of success since N-vinylpyrrolidone is commonly used as a film-forming polymer in cosmetic formulations. It would be within the knowledge of one of ordinary skill in the art to substitute it for an acrylic polymer used for the same function.

Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535) in view of Trenzeluk (US Patent 4,857,328).

Lundmark's teachings as they apply to Claim 1 are described above.

Lundmark does not disclose the use of antioxidants, transretinoic acid and/or derivatives and precursors thereof, polyunsaturated fatty acids, n-hexacosanol, bis(maltolato)oxo-vanadium(IV), aloe vera, and thickeners. Lundmark also does not disclose a percentage of additives.

Trenzeluk discloses "a skin therapeutic mixture is useful for the alleviation of certain skin disorders such as acne, psoriasis, burns, pimples, blackheads, and open sores: the therapeutic agent being the extract from the dried leaves of the aloe vera plant; the skin therapeutic mixture comprises about 7.4% by weight of the extract from the dried leaves of the aloe vera plant as the therapeutic agent" (abstract).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have added aloe vera to a skin care composition, since aloe is well known in the art for its soothing effects, fragrance, and healing qualities.

The applicant would have a reason expectation of success since the use of aloe vera is well known in the art for the same reasons and qualities applicant is claiming.

Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535) in view of Hymes et al. (US Patent 4,307,717).

Lundmark's teachings as they apply to Claim 1 are described above.

Lundmark does not disclose the honey being sterilized with the use of gamma rays.

Hymes discloses a liquid absorbent, adhesive bandage, in which the combination of the mixture is then subjected to irradiation (usually gamma rays) usually to 2.5 mega rads for sterilization (column 2, lines 65-67).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have used the sterilization method taught by Hymes on the composition taught by Lundmark in order to make a composition which is suitable for direct contact with the skin to cover surgical wounds or burn tissue" (Hymes, column 2, lines 23-27).

Applicant would have a reasonable expectation of success in the sterilization of a composition using gamma rays, since irradiation with gamma raise is known in the art as being effective.

Response to Arguments

Applicant's arguments filed April 2, 2007 have been fully considered but they are not persuasive. Applicant argues Lundmark does not disclose a honey-based wound treatment preparation. It is the examiners position that Lundmark discloses a honey based composition suitable for dermatological use; therefore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicant additionally argues Lundmark does not anticipate a honey for a treatment of wounds, which comprises a polymeric gel for absorbing moisture. The examiner disagrees, Lundmark discloses the same composition as instant claims, therefore, and it would possess the same properties as the instantly claimed composition. The prior art differs only by the percentages of each component present. It is well within the knowledge of one of ordinary skill in the art to optimize the percentage of each component in order to arrive at a composition with the desired properties.

Applicant has not provided any arguments regarding the combination of references over Lundmark.

Conclusion

No claims are allowable. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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